#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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MDL No. 1456 23 JL 18 A 10:45 IN RE PHARMACEUTICAL INDUSTRY Civil Action 01-CV-12257-PBS COURT **AVERAGE WHOLESALE PRICE** LITIGATION Judge Patti B. Saris THIS DOCUMENT RELATES TO: Rice v. Abbott Laboratories, Inc., No. 3:02-cv-3925, (N.D. Cal.), Thompson v. Abbott Laboratories, Inc., No. 3:02-cv-4450 (N.D. Cal.), and Turner v. Abbott Laboratories, No. 3:02-cv-5006 (N.D. Cal.)

#### DEFENDANT MYLAN LABORATORIES INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS

Defendant Mylan Laboratories Inc. ("Mylan"), through the undersigned counsel, respectfully submits Mylan's memorandum of law in support of its motion to dismiss.

#### I. Mylan Incorporates Unnamed Defendants' Consolidated Motion To Dismiss

Mylan adopts and incorporates by reference the arguments set forth in the consolidated Motion to Dismiss the Unnamed Defendants ("Consolidated Motion"). While Mylan has not been named in the Amended Master Consolidated Complaint ("AMCC"), the complaints in Rice, Thompson, and Turner ("California complaints") do nothing more than generally state that Mylan is a generic drug manufacturer that sells unspecified pharmaceuticals in California. Rice Compl. ¶ 43; Thompson Compl. ¶ 43; Turner Compl. ¶ 34. Neither the AMCC nor the California complaints identify (1) any drug manufactured by Mylan by name, (2) a single Plaintiff who purchased a specified drug manufactured by Mylan, or (3) an inflated average wholesale price ("AWP") attributable to a drug manufactured by Mylan. Because Plaintiffs have failed to meet each of those requirements,

Mylan should be dismissed from the AMCC and California Complaints. *See* Court's Memorandum and Order ("Opinion") dated May 13, 2003 at 3, 45. Moreover, the California complaints fail to comport with the Opinion insofar as they seek to encompass generic multisource drugs. *Id.* at 45-46. Because no single manufacturer's AWP can determine the Medicare payment for a generic drug, 42 C.F.R. § 405.517(c), Plaintiffs, as a matter of law, cannot establish that Mylan caused any alleged inflation to AWPs. For the same reasons that the Court has already dismissed claims concerning generic drugs, Plaintiffs' claims against Mylan should not survive.

## II. For Additional Reasons, The California Complaints Should Be Dismissed In Whole Or In Part

To the extent that the allegations contained in the California complaints have not been superseded, Plaintiffs' claims against Mylan should be dismissed for the following additional reasons:

#### A. Plaintiffs' UCL Claim Should Be Dismissed Because Congress Has Permitted The Alleged Conduct in Question

With full knowledge that AWPs usually do not represent the actual acquisition costs paid by medical providers, Congress has considered the structure of the Medicare Part B reimbursement system and has deliberately retained AWP as the reimbursement benchmark. See Consolidated Memorandum in Support of Defendants' Motion to Dismiss the Master Consolidated Class Action Complaint at 3-14 (Nov. 25, 2002). In 1997, after conducting extensive hearings, Congress rejected proposals to set reimbursement at providers' actual acquisition costs and modified the Medicare Part B statute by reducing reimbursement from 100% of AWP to 95% of AWP. 42 U.S.C. § 1395u(o); see also Rice Compl. ¶ 71 (federal regulation and industry practice provide that reimbursement is based upon reported AWP);

Thompson Compl. ¶ 71 (same); Turner Compl. ¶ 63 (same). As AWP-based reimbursement has been considered and approved of by Congress, the practice of reporting AWPs falls within a safe harbor under the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq. ("UCL"); therefore, the California complaints should be dismissed.

According to the California Supreme Court, "the UCL cannot be used to state a cause of action the gist of which is absolutely barred under some other principle of law." Stop Youth Addiction, Inc. v. Lucky Stores, Inc., 17 Cal.4th 553, 566 (1998). Where a legislature has permitted certain conduct or considered a situation and concluded that no action should lie, a "safe harbor" exists which may not be circumvented by use of the UCL. Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co., 20 Cal.4th 163, 182 (1999). "Acts that the Legislature has determined to be lawful may not form the basis for an action under the unfair competition law...." Id. at 183. "[C]ourts may not use the unfair competition law to condemn actions the Legislature permits[,]" nor may plaintiffs "plead around" a "safe harbor." Id. at 184; see also Olszewski v. Scripps Health, 30 Cal.4th 798 (June 2, 2003).

The safe harbor rule has been applied to circumstances where (1) the business practice in question is statutorily permitted, *Olszewski*, 30 Cal.4th at \*61-67; *Swanson v. St. John's Reg'l Med. Ctr.*, 97 Cal.App.4th 245, 248 (2002); (2) the defendants' alleged unfair business practices arise from the claimed violation of non-existent statutory duties, *California Med. Ass'n, Inc. v. Aetna U.S. Healthcare of Cal., Inc.*, 94 Cal.App.4th 151, 169 (2001), (3) judicially-created doctrine allows the conduct, *Chavez v. Whirlpool Corp.*, 93 Cal.App.4th 363, 375 (2001), and (4) a legislature has considered a situation and chosen not to prohibit the questioned activity, indicating a legislative intent to permit the conduct. *Schnall v. Hertz Corp.*, 78 Cal.App.4th 1144, 1162 (2000). Where the alleged conduct is

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insulated from a UCL claim, dismissal is proper. *Olszewski*, 30 Cal.4th at \*6, 67; *Chavez*, 93 Cal.App.4th at 367, 375.

Permitting plaintiffs to proceed under the UCL would render meaningless Congress' express determinations concerning the propriety of the AWP-based reimbursement system. The Court should not endeavor to prohibit what the legislature has consciously permitted and refused to change, and the UCL should not be interpreted so broadly as to reach conduct that Congress has addressed and decided not to proscribe. The California complaints, which are entirely premised under the UCL, should be dismissed.

#### B. Plaintiffs' Allegations Of Unlawful Conduct Fail As A Matter of Law

Plaintiffs' UCL claim is based in part on allegations of unlawful business practices. Rice Compl. ¶ 90; Thompson Compl. ¶ 90; Turner Compl. ¶ 76. To sustain such an allegation under the UCL, a plaintiff must allege the violation of some underlying statute or regulation other than the UCL. Farmers Ins. Exch., v. Superior Court, 2 Cal.4th 377, 383 (1992); Saunders v. Superior Court, 27 Cal.App.4th 832, 838-39 (1994). Plaintiffs fail to specify the violation of any predicate statute or regulation; therefore, all allegations based on unlawful business practices should be stricken.

# C. Plaintiffs' Allegations That Mylan Acted As A Coconspirator Should Be Stricken

Plaintiffs aver generally that each of the defendant drug manufacturers was the agent, servant, partner, aider and abettor, coconspirator and/or joint venturer of each of the remaining Defendants in connection with the alleged false reporting of AWPs. *Rice* Compl. ¶¶ 58-59; *Thompson* Compl. ¶¶ 58-59; *Turner* Compl. ¶¶ 47-48. However, Plaintiffs have failed to allege a factual basis for any such claims against Mylan. For instance, a conspiracy claim requires (1) formation and operation of conspiracy, (2) wrongful conduct in

furtherance of conspiracy, and (3) damages arising from wrongful conduct. See Sebastian

Int'l, Inc. v. Russolillo, 162 F.Supp.2d 1198, 1207 (C.D. Cal. 2001). To establish a joint

venture, a plaintiff must demonstrate an agreement between parties under which they have

(1) a joint interest in a common business undertaking, (2) an understanding to share profits,

and (3) a right of joint control in the enterprise. See Jackson v. East Bay Hosp., 246 F.3d

1248, 1261 (9th Cir. 2001). Plaintiffs have failed to allege any facts against Mylan to

substantiate these allegations; therefore, the above allegations should be dismissed.

D. Plaintiffs Are Barred From Seeking Damages And Attorneys' Fees

In their complaints, Plaintiffs impermissibly seek compensatory, special, incidental

and punitive damages. Rice Compl. Prayer for Relief at 27-28; Thompson Compl. Prayer for

Relief at 27-28; Turner Compl. Prayer for Relief at 17. Plaintiffs' also request attorneys'

fees. Id. It is clear, however, that the UCL only recognizes equitable relief and does not

authorize the recovery of attorneys' fees. Cel-Tech, 20 Cal.4th at 179. Plaintiffs' request for

damages and attorneys' fees should, therefore, be stricken.

**CONCLUSION** 

WHEREFORE, Mylan respectfully requests that Mylan be dismissed with prejudice

from the AMCC and California complaints.

Dated: July 18, 2003

Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

The undersigned certifies that a true and correct copy of Defendant Mylan Laboratories Inc.'s Memorandum of Law in support of Motion to Dismiss was served on all counsel of record via electronic service pursuant to Case Management Order No. 2 on July 18, 2003.

Ryan James